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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,977	07/27/2001	Ben C. Askew	20009YDB	9107

210 7590 10/07/2003

MERCK AND CO INC  
P O BOX 2000  
RAHWAY, NJ 070650907

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/916,977

Applicant(s)

ASKEW ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-51, and 53-63 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's amendment of 5-19-03 has been considered. The proviso has been deleted from claims 41-43. Thus, the previous "New Matter" rejection under 112/1<sup>st</sup> paragraph is withdrawn. Because the dependency of claim 43 has been corrected, the rejection of 112/2<sup>nd</sup> is also withdrawn.

However, applicant's argument seems to need clarification on the previous rejection of "Scope of Enablement". Therefore, the previous rejection of "Scope of Enablement" is replaced by a new "Scope of Enablement" rejection. Regarding the double patenting rejection, the co-pending application, 09/767,471, has been allowed. Thus, the double patenting rejection is maintained until a terminal disclaimer is filed.

An updated search yields a new reference, which prompts the following new ground of rejection.

Claims 41-63 are pending.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 41-51, and 53-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the **preparation and use** of the

claimed pyrimidinyl compounds with **R<sup>5</sup> (or R<sup>6</sup>) as a quinolinyl ring {while R<sup>7</sup> and R<sup>8</sup> are hydrogen atoms}**, does not reasonably provide enablement for the preparation and use of the remaining pyrimidinyl compounds (i.e., those with R<sup>5</sup>-R<sup>8</sup> as anything else). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As stated in the previous action, only Scheme 26 describes the reaction sequence for making the claimed **pyrimidinyl** compounds with R<sup>5</sup> (or R<sup>6</sup>) as a **quinolinyl** ring {while R<sup>7</sup> and R<sup>8</sup> are hydrogen – i.e., the preparation of compound 26-6}. Said preparation requires intermediate 5-7, which is specific to compound 26-6, and **not** to other pyrimidinyl compounds (having R<sup>5</sup>-R<sup>8</sup> as anything else). Thus, the specification provides the guidance for preparing only **a limited set of pyrimidinyl compounds** (i.e., those substituted with a quinolinyl ring).

Applicants asserts that the specification provides other functional groups, and/or rings as intermediates represented by one of R<sup>5</sup>-R<sup>8</sup> as well. However, it is noted that said intermediates are used in the preparation of **naphthyridinyl** compounds, and **not** pyrimidinyl compounds claimed herein. The specification **does not suggest that those intermediates can be used in place** of intermediate 5-7 to make other pyrimidinyl compounds.

Furthermore, among different reaction schemes for making naphthyridinyl compounds, it is noted that different combination of reagents, and reaction conditions are required for the addition of different intermediates. Note, even the addition of intermediate 5-7 to a naphthyridinyl compound uses reagents that are **not** required for the addition of the same intermediate to a pyrimidinyl compound. Thus, even if other intermediates are disclosed (for one

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of R<sup>5</sup>-R<sup>8</sup>) in the preparation of **naphthyridinyl** compounds, to add them to a **pyrimidinyl** compound, one would have to carry out undue experimentation to find the **right combination of reagents, and/or reaction conditions**.

With the broad scope of claim 41 allowing R<sup>5</sup>-R<sup>8</sup> to be anything from hydrogen to various functional groups and/or rings, one skilled in the art must first make the appropriate intermediate, then finds the right reagents and reaction conditions to add it to a pyrimidinyl compound. Such a task undoubtedly needs undue experimentation since the guidance in the specification, and the state of the art is inadequate.

Regarding the biological activity, since it appears that only **one pyrimidinyl compound** (i.e., compound 26-6) is made and presumably tested, there is insufficient evidence to conclude that other pyrimidinyl compounds would share the same biological activity. Thus, given the unpredictable nature of the art, and the vast number of pyrimidinyl compounds claimed herein, one skilled in the art would have to carry out undue experimentation to figure out which compounds possess the same activity as the one actually made and tested.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 41, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by **Gronowitz et. al.** (Arkiv foer Kemi, 1967, Vol. 28, No. 38, pp. 587-602 – see CAS print out). Gronowitz et. al. disclose a compound of “4-Pyrimidinevaleric acid” which is embraced by the claimed formula with the following substituents:

- a. X represents pyrimidinyl with R<sup>1</sup> as hydrogen;
- b. Y does not exist (i.e., Y is (CH<sub>2</sub>)<sub>m</sub>, with m = 0);
- c. R<sup>5</sup>-R<sup>9</sup> are hydrogen.

Since it appears that the disclosed compound does not have a therapeutic use, the pharmaceutical composition and method claims are not anticipated by said reference.

#### ***Claim Objections***

3. Claim 52 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1<sup>st</sup> -03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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October 2, 2003



ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600